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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,317	02/05/2001	Hermann Bujard	BBI-013C3CN3	3698
959	7590	06/04/2003		
LAHIVE & COCKFIELD			EXAMINER	
28 STATE STREET			SHUKLA, RAM R	
BOSTON, MA 02109				
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/777,317	BUJARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 11 March 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 18-22 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 18-22 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 2-5-01 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

#### **DETAILED ACTION**

1. Amendment and response filed 3-11-03 have been entered.
2. Claims 1-17 have been cancelled.
3. Applicant's election without traverse of the invention of group III, claims 18-22 in Paper No. 11 is acknowledged. It is noted that by error applicants have indicated claims 19-22 as elected invention.
4. Claims 18-22 are pending and under consideration.

#### ***Priority***

5. It is noted that the priority statements in the transmittal letter, in the first paragraph of the specification and in the preliminary amendment filed 2-05-01 do not match up. In the transmittal sheet the instant application is listed as a continuation of 09/163, 276, however, in the preliminary amendment of 2-5-01 is listed as a continuation of 08/479306. Applicants are required to correct the priority information in the first sentence of the application.

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 18-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S.

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Patent No. 6,136,954. Although the conflicting claims are not identical, they are not patentably distinct from each other because both cited US patent and the instant application recite a fusion protein comprising a first polypeptide that is Tet repressor that is operatively linked to second polypeptide which activates transcription in eukaryotic cells. It is noted that the cited US patent recites that the first polypeptide binds to a tet operator sequence whereas the claim in the instant application does not recite this limitation. Therefore, while the scope of the claims in the instant application and that in the cited patent are different, the invention of claims 18-22 of the instant application are encompassed by the invention of claim 1 of the cited US patent.

8. No claim is allowed.

9. Examiner's Comments:

This application is a continuation of the US Serial No. 09/163,276, filing date 9-29-98 (now abandoned). In this parent application 112 first paragraph enablement rejection was set forth which was argued by applicants and examiner agreed to withdraw the enablement rejections in view of applicants' arguments. However, an issue of double patenting against US patent 6,136,954 was raised. While applicants filed a Terminal Disclaimer (TD), the TD has errors and therefore was not considered to be proper. Later on the application was abandoned and continuation was filed. During a telephonic conversation on 3-21-01 with Peter Dini and Elizabeth Henley, Ms. Henley indicated that a TD will be filed in the continuation application. However, no TD has been filed in the instantly pending application. Accordingly, the double patenting rejection is set forth. Filing of a proper TD will obviate the double patenting rejection and claims as instantly pending will be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



RAM SHUKLA  
PRIMARY EXAMINER